

REMARKS

This Amendment is submitted in response to the final Office Action mailed on March 18, 2009. No fees are due herewith. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 0115808-00511 on the account statement.

Claims 38-53, 55 and 58-71 are pending in this application. Claims 1-37 and 54-57 were previously canceled. Claims 38-47 and 61-71 were previously withdrawn. In the Office Action, Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. §112. Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. §102 and 103. In response, Claims 48-49, 55, 58 and 60 have been amended and Claims 50-51 have been canceled without prejudice or disclaimer. The amendments do not add new matter. In view of the amendment and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. §112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Patent Office asserts that the claims contain the language "pancreatic extract," which is "indefinite." The Patent Office asserts that it is unknown what a pancreatic extract is and that Applicants have not properly defined the term "pancreatic extract" in the instant specification. See, Office Action, page 2, lines 13-19. Applicants respectfully submit that one of ordinary skill in the art would immediately appreciate what is meant by the phrase "pancreatic extract" when read in view of the specification.

For example, extracts are essentially concentrated portions of a material obtained by extracting a part of a raw material typically by using a solvent such as, for example, ethanol or water. Applicants respectfully submit that the skilled artisan would immediately appreciate that there are a number of ways to obtain a pancreatic extract, but that the end result (*i.e.*, the pancreatic extract from pancreatic material) will remain the same. Moreover, Applicants submit that the written description need not disclose each and every process for extracting a pancreatic extract, or even a specific definition for a "pancreatic extract" because patent specifications typically omit what is known in the art. Specifically, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). Indeed, the skilled artisan would immediately appreciate that a pancreatic extract is an extract of pancreatic material obtained by extracting a part of the pancreatic material.

As such, Applicants respectfully submit that it is not necessary for Applicants to recite a specific definition of “pancreatic extract,” as is implied by the Patent Office. Instead, when the present claims are read in view of the specification, the skilled artisan would immediately appreciate that a pancreatic extract is an extract of pancreatic material obtained by extracting a part of the pancreatic material.

Therefore, Applicants respectfully submit that a specific definition of “pancreatic extract” is not required in order for the present claims to fully comply with the requirements of 35 U.S.C. §112, second paragraph. For at least these reasons, Applicants submit that Claims 48-53, 55 and 58-60 fully comply with the requirements of 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejections of Claims 48-53, 55 and 58-60 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

In the Office Action, Claims 55, 58 and 60 are rejected under 35 U.S.C. §112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Patent Office asserts that the “claims contain the language ‘wherein the component’ which is indefinite.” See, Office Action, page 3, lines 1-4. In response, Applicants note that Claim 55 has been amended to recite, in part, a regimen according to claim 48 wherein the intestinal mucosa function-promoter further comprises a fat transportation agent; Claim 58 has been amended to recite, in part, a regimen according to claim 55 wherein the fat transportation agent has a fatty acid profile; and Claim 60 has been amended to recite, in part, a regimen according to claim 58 wherein the fat transportation agent comprises whey protein. The amendments do not add new matter. The amendments are supported in the specification at, for example, page 7, lines 1-19. In contrast to the Patent Office’s assertion that it is confusing as to whether there is a secondary intestinal mucosa function promoter, Applicants respectfully submit that the skilled artisan would immediately appreciate the scope of the present claims when read in view of the specification.

For example, independent Claim 48 recites, in part, that the intestinal mucosa function-promoter “comprises” an omega-3 fatty acid derived from fish oils. Accordingly to the Manual of Patent Examining Procedure (MPEP), the word “comprises” does not exclude the intestinal mucosa-function promoter from having other ingredients as well. Accordingly, Claims 55, 58 and 60 have now been amended to clarify that the intestinal mucosa-function promoter may further include a fat transportation agent. For at least these reasons, Applicants submit that

Claims 48-53, 55 and 58-60 fully comply with the requirements of 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejections of Claims 48-53, 55 and 58-60 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

In the Office Action, Claims 48-50, 52-53 and 58 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,369,252 to Akoh ("*Akoh*"). Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. §102(b) as being anticipated by EP 1 048 226 to Kratky et al. ("*Kratky*"). Claims 48 and 58-59 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,228,367 to Watson ("*Watson*"). Claims 48-52 and 58-59 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,576,667 to Strohmaier et al. ("*Strohmaier*"). In contrast, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Currently amended independent Claim 48 recites, in relevant part, a composition comprising a first pancreatic function promoter, a second pancreatic function promoter, and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract, and the second pancreatic function promoter is a gut pH modifier selected from the group consisting of a prebiotic, a probiotic and combinations thereof. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 6, lines 28-29. In contrast, Applicants respectfully submit that *Akoh*, *Kratky*, *Watson* and *Strohmaier* all fail to disclose or suggest each and every element of the present claims.

For example, *Akoh*, *Kratky*, *Watson* and *Strohmaier* all fail to disclose or suggest a composition comprising a first pancreatic function promoter, a second pancreatic function promoter, and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract, and the second pancreatic function promoter is a gut pH modifier selected from the group consisting of a prebiotic, a probiotic and combinations thereof as required, in part, by the present claims. Instead, *Akoh* is entirely directed to novel structured lipids that are formed by combining fatty acids and lipases by enzymatic methods. See, *Akoh*, column 2, lines 42-44. *Kratky* is entirely directed to an infant formula containing sweet whey protein, a lipid source and a carbohydrate source. See, *Kratky*, Abstract. *Watson* is entirely directed toward a food supplement formulation comprising flaxseed oil, borage seed oil, fish oil, and lipase. See, *Watson*, Abstract. *Strohmaier* is entirely directed toward methods for preparing fatty acid calcium salts including certain specific steps. See, *Strohmaier*, Abstract.

Accordingly, *Akoh, Kratky, Watson and Strohmaier* all fail to disclose or suggest a composition comprising a first pancreatic function promoter, a second pancreatic function promoter, and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract, and the second pancreatic function promoter is a gut pH modifier selected from the group consisting of a prebiotic, a probiotic and combinations thereof as required, in part, by the present claims.

Further, anticipation is a factual determination that “requires the presence in a single prior art disclosure of each and every element of a claimed invention.” *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, e.g., *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. For at least these reasons, Applicants respectfully submit that *Akoh, Kratky, Watson and Strohmaier* all fail to anticipate the presently claimed subject matter.

For at least the reasons discussed above, Applicants respectfully submit that Claims 48-53, 55 and 58-60 are novel, nonobvious and distinguishable from the cited reference and are in condition for allowance.

Therefore, Applicants respectfully request that the rejection of Claims 48-53, 55 and 58-60 under 35 U.S.C. §102 as anticipated be reconsidered and withdrawn.

In the Office Action, Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,471,999 B2 to Couzy et al. (“*Couzy*”) in view of JP 408038063A to Reinhart (“*Reinhart*”) or US 2001/0051206 A1 to Hayek et al. (“*Hayek*”). In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Independent Claim 48 recites, in part, a nutrition management regimen comprising a dietary component comprising a first pancreatic function promoter and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract. See, Specification, page 11, lines 8-15. Several studies have shown that older pets, especially cats, have a decreased capacity to digest lipids. See, Specification, page 1, paragraph 4, lines 1-5. Because valuable nutrients such as vitamins A, D, E and K are absorbed only with long-chain fatty acids, a decrease in the ability to digest lipids can lead to vitamin deficiencies and adverse

health effects on a pet. See, Specification, page 1, paragraph 8, lines 1-4 and 10-12. Therefore, the present claims provide a dietary composition for a pet that contains a pancreatic extract and an intestinal mucosa function-promoter in an amount effective to increase the capacity of the pet to digest lipids. See, Specification, page 2, paragraph 18, lines 1-8. In contrast, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

For example, *Couzy*, *Reinhart*, and *Hayek* all fail to disclose or suggest a nutrition management regimen comprising a dietary component comprising a first pancreatic function promoter and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract as is required, in part, by the present claims. Instead, *Couzy* is directed merely to reducing the gastrointestinal problems associated with the consumption of lactose. See, *Couzy*, col. 2, lines 1-4. The addition of lactase improves the general gastrointestinal tolerance of the pets. See, *Couzy*, col. 2, lines 1-9. In contrast, the present claims include an intestinal mucosa function-promoter in an amount effective to specifically increase the capacity of a pet to digest lipids. See, Specification, page 2, paragraph 18, lines 5-8. *Reinhart* is entirely directed to a product containing a specific ratio of omega-6 and omega-3 fatty acids to decrease the inflammatory response of skin. See, *Reinhart*, Abstract, Purpose, lines 1-4. Similarly, *Hayek* is completely directed to a pet food composition for reducing the inflammatory response in cats. See, *Hayek*, Abstract, lines 1-2. *Gluck* is entirely directed toward a treat for pets having a certain composition and including whey protein. The treats are palatable to pets and are based on vegetarian products and contain nutraceutical ingredients. See, *Gluck*, Abstract; col. 1, lines 6-10.

At no place in the disclosures do any of *Couzy*, *Reinhart*, *Hayek* or *Gluck* disclose or suggest a nutrition management regimen comprising a dietary component comprising a first pancreatic function promoter and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract as required, in part, by the present claims.

Accordingly, Applicants respectfully request that the rejections of Claims 48-53, 55 and 58-60 as being unpatentable over *Couzy*, *Reinhart*, and *Hayek* be reconsidered and withdrawn.

In the Office Action, Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 02/15719 to Fuchs et al. ("*Fuchs*") in view of *Reinhart* or *Hayek*. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

As discussed above, independent Claim 48 recites, in part, a nutrition management regimen comprising a dietary component comprising a first pancreatic function promoter and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract. In contrast, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Fuchs, *Reinhart*, and *Hayek* all fail to disclose or suggest a nutrition management regimen comprising a dietary component comprising a first pancreatic function promoter and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract for substantially the same reasons set forth above. Further, *Fuchs* fails to remedy the deficiencies of the secondary references discussed above because *Fuchs* also fail to disclose or suggest a nutrition management regimen comprising a dietary component comprising a first pancreatic function promoter and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract. Instead, *Fuchs* is entirely directed toward a composition for a nutritional supplement for convalescing patients recovering from illness or surgery, those with limited appetite such as the elderly, children or anorexic patients, or those who have impaired ability to digest other sources of protein. See, *Fuchs*, Abstract. At no place in the disclosure does *Fuchs* disclose or even suggest a nutrition management regimen for administration to a pet animal comprising a dietary component comprising a first pancreatic function promoter and an intestinal mucosa function-promoter, wherein the first pancreatic function promoter is a pancreatic extract. In fact, *Fuchs* is entirely directed toward administration of a composition to humans and does not even mention that the composition may be administered to pet animals as is required, in part, by the present claims. Therefore, Applicants respectfully submit that the combination of *Fuchs*, *Reinhart*, and *Hayek* fails to disclose or suggest each and every element of the present claims.

Accordingly, Applicants respectfully request that the rejections of Claims 48-53, 55 and 58-60 under 35 U.S.C. §103(a) as being unpatentable in view of *Fuchs*, *Reinhart*, and *Hayek* be reconsidered and withdrawn.

Further, in the Office Action, the Patent Office asserts that “Applicants argued that ‘999 or ‘719 in view of ‘206 or ‘063 does not teach a pancreatic promoter such as pancreatic extract, however, the instant specification Example 2 a preferred pancreatic promoter exemplified is taurine.” See, Office Action, page 11, lines 15-17. However, Applicants respectfully submit that the Patent Office’s assertion is irrelevant in view of the present claims. For example, the present

claims do not simply recite that the composition includes "a pancreatic function promoter." Instead, the present claims specifically require that the first pancreatic function promoter is specifically "a pancreatic extract." Applicants submit that taurine, a naturally occurring sulfonic acid found in the lower intestine, is not a pancreatic extract.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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